



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Thursday, April 07, 2005

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 69268-3 / H<sub>2</sub>Orange 120  
Ready-To-Use  
DP Barcode: D311541

To: Marshall Swindell, PM 33/ Tony Kish  
Regulatory Management Branch  
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist *Ian Blackwell*  
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4/7/05

Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510C)

Applicant: Envirox, LLC.

FORMULATION FROM LABEL:

Active Ingredient(s):

Hydrogen peroxide

Other Ingredient(s):

% by wt.

1.00

99.00

Total:

100.00%

- 1) BACKGROUND: Envirox, LLC, has submitted a request for a change of the acute toxicity profile of their product, "H<sub>2</sub>Orange 120 Ready-To-Use". This request was previously assessed in a 1/7/2003 CTT/PSB/AD review of this same product. The results of that study were:

Study	Toxicity Category	Status
Acute Oral Toxicity	III	Acceptable
Acute Dermal Toxicity	III	Acceptable
Acute Inhalation Toxicity	III	Acceptable
Primary Eye Irritation	IV	Acceptable
Primary Skin Irritation	IV	Acceptable
Dermal Sensitization	Nonsensitizer	Acceptable

- a) The acute oral and dermal toxicity studies were rejected as the test material was listed as H<sub>2</sub>Orange 126, not H<sub>2</sub>Orange 120 (the registration product).
- b) Also, the registrant wanted to have their product assigned toxicity category IV for acute inhalation toxicity; however, they did not submit replacement acute inhalation toxicity data.

In this submission, the registrant writes to explain the designation of H<sub>2</sub>Orange 126. They state that it is actually a chemically similar product with the most of the same ingredients as H<sub>2</sub>Orange 120, but in difference concentrations. MRID Number 464041-02 details this information. For the comparison of the two formulations, please refer to that report.

- 2) RECOMMENDATIONS: PSB findings are:

- a) CTT/PSB/AD will not allow the studies conducted on H<sub>2</sub>Orange 126 to be used to support labeling for H<sub>2</sub>Orange 120. While the two formulations are similar, they are not exactly the same. The main point that separates the two products, in the view of CTT/PSB/AD, is the difference in the acute toxicity profiles of the two products. CTT/PSB/AD does not understand how the registrant expects to replace existing data on their product with acute toxicity data from another, non-existent product.
- b) The registrant has still apparently not submitted an acute inhalation toxicity data to change the profile. This is not a problem for CTT/PSB; however, it will not change the product's acute toxicity profile as the registrants have indicated that they want to.

The acute toxicity profile for Registration Number 69268-3 is currently:

Study	Toxicity Category	Grade
acute oral toxicity	III	acceptable
acute dermal toxicity	III	acceptable
acute inhalation toxicity	III	acceptable
primary eye irritation	IV	acceptable
primary skin irritation	IV	acceptable
dermal sensitization	nonsensitizer	acceptable

3) LABELING:

- a) The signal word is "Caution".
- b) The Precautionary Statements should state:

"Harmful if swallowed, inhaled or absorbed through skin. Avoid contact with skin, eyes, or clothing. Avoid breathing (dust, vapor, or spray mist). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

- c) The First Aid Statements should state:

IF SWALLOWED:

- Call a Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a Poison Control Center or doctor.
- Do not give anything by mouth to an unconscious person.

IF ON SKIN:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for treatment advice.

IF INHALED:

- Move person to fresh air.
- If not breathing, call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a Poison Control Center or doctor for treatment advice.